DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 26, 2015

Graham Medical Technologies, LLC (d.b.a.GraMedica)
% Linda Braddon, Ph.D.
Secure BioMed Evaluations
7828 Hickory Flat Highway Suite 120
Woodstock, Georgia 30188

Re: K142478
Trade/Device Name: opti-Toe
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY
Dated: April 27, 2015
Received: April 28, 2015

Dear Dr. Braddon:

This letter corrects our substantially equivalent letter of May 29, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142478

Device Name
opti-Toe

Indications for Use *(Describe)*
The GraMedica opti-Toe Device is indicated for reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe. The GraMedica opti-Toe components are to be cemented in place and assembled for reconstruction of the toe. Patients should protect their weight-bearing or heel weight-bearing only until soft tissue healing has occurred.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510 (k) Summary

In accordance with 21 CFR 807.87 (h) and 21 CFR 807.92, the 510(k) summary for the GraMedica opti-Toe is provided below.

Date	5/22/2015
Sponsor	GraMedica 16137 Leone Drive Macomb, MI 48042 586-677-9600 (office) 586-677-9615 (fax) ARecchia@GraMedica.com (email)
510(k) Contact	Secure BioMed Evaluations Linda Braddon, Ph.D. 7828 Hickory Flat Highway Suite 120 Woodstock, GA 30188 770-837-2681 (direct) 855-MED-DEV1 (office) LGB@SecureBME.com
Trade Name	opti-Toe
Common Name	Pin, fixation, smooth
Code–Classification	**HTY** 21 CFR 888.3040 : Class II
Predicate Devices	K122031 Nextra™ Ti Hammertoe Correction System K142490 ProxiFuse Hammer Toe Device
Reference Devices	K990804 StayFuse K960385 DePuy K-Wire
Device Description	The GraMedica opti-Toe is comprised of two mated components (proximal and middle phalangeal) which join together to form a single intramedullary fixation unit. The implants are offered in two sizes, small and large, and the middle phalangeal component is offered with and without a 10 degree angulation.
Intended Use	The GraMedica opti-Toe Device is indicated for reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe. The GraMedica opti-Toe components are to be cemented in place and assembled for reconstruction of the toe. Patients should protect their weight-bearing or heel weight-bearing only until soft tissue healing has occurred.
Technological Characteristics	The GraMedica opti-Toe is of similar sizes, material choices and configurations as compared to the predicate. The GraMedica opti-Toe is to be cemented.
Non-Clinical Performance Testing Conclusion	The GraMedica opti-Toe was tested for clinical ease of use via: • Cadaveric Simulated Use Study • Assembly force • Disassembly force Additionally, mechanical performance was evaluated via: • Static and dynamic bending
Substantial Equivalence Summary	Based on the indications for use, technological characteristics, and comparison to predicate devices, the GraMedica opti-Toe is shown to be

(Conclusion)	substantially equivalent to legally marketed predicate devices, and safe and effective for its intended use.